



20 May 2021
EMA/CHMP/SAWP/284236/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 17 – 20 May 2021

Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures

	1995-2020	2021	Overall total
Scientific Advice	4766	227	4993
Follow-up to Scientific Advice	1413	128	1541
Protocol Assistance	1076	41	1117
Follow-up to Protocol Assistance	576	22	598
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	10	171
	8157	363	8585

Outcome of the May 2021 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of COVID-19 disease	x						x	
Chemical	Prevention of Covid-19 disease	x						x	
Biological	Prevention of Covid-19 disease	x				x	x	x	

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Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of Covid-19 disease	x				x		x	
Biological	Treatment of COVID-19		x			x			
Biological	Prevention of Covid-19 disease		x			x	x		
Qualification advice	Prevention of type I diabetes							x	
Qualification advice	Multiple sclerosis protocol							x	
Qualification advice	Statistical adjustment on deep learning prognosis covariates							x	
Chemical	Treatment of NSCLC	x				x			
Chemical	Treatment of glomerulosclerosis			x		x	x	x	
Biological	Treatment of myeloid leukaemia				x			x	
Chemical	Treatment of post-traumatic stress disorder	x					x	x	
Chemical	Treatment of prostate cancer	x						x	
Biological	Treatment of COVID-19 disease	x				x	x	x	
Chemical	Treatment of anaemia	x						x	
Biological	Treatment of Guillain-Barre syndrome	x						x	
Biological	Treatment of macular degeneration	x				x			
Chemical	Treatment of anaemia		x					x	
Biological	Treatment of ulcerative colitis	x						x	
Biological	Treatment of hypercholesterolaemia	x						x	
Chemical	Treatment of tachycardia		x				x	x	
Biological	Treatment of thrombosis	x					x	x	
Chemical	Treatment of solid tumours and lymphomas	x				x			
Chemical	Prevention of complications in renal disease	x				x	x	x	
Chemical	Treatment of Huntington's disease	x				x	x	x	
Biological	Treatment of colorectal cancer	x					x	x	
Biological	Treatment of Alzheimer's disease	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of mitochondrial myopathies	x				x			
Chemical	Treatment of lymphocytic leukaemia	x						x	
Chemical	Treatment of urinary tract infection	x				x	x	x	
Advanced Therapy	Treatment of DLBCL	x						x	
Chemical	Treatment of schizophrenia		x					x	
Chemical	Treatment of Infarction		x					x	
Chemical	Treatment of prostate cancer	x				x			
Chemical	Treatment of pulmonary disease		x					x	
Biological	Treatment of biliary track carcinoma	x					x		
Chemical	Treatment of myeloid leukaemia		x					x	
Biological	Treatment of large B-cell lymphoma	x						x	
Chemical	Treatment of Duchenne muscular dystrophy			x			x	x	
Chemical	Treatment of COPD	x				x	x	x	
Biological	Treatment of spinal muscular atrophy			x		x	x		
Chemical	Treatment of cardiomyopathy				x			x	x
Chemical	Treatment of syncytial virus infections	x				x		x	
Chemical	Prophylaxis of bleeding episodes				x			x	
Biological	Treatment of breast cancer		x			x		x	
Chemical	Prevention of vaso-occlusive crises		x					x	
Biological	Prevention of ExPEC disease	x				x	x	x	
Biological	Treatment of myopathies	x						x	
Biological	Treatment of headache	x						x	
Chemical	Treatment of osteosarcoma			x			x	x	
Chemical	Treatment of amyotrophic lateral sclerosis			x			x		

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of HPV virus diseases	x				x	x	x	
Biological	Prevention of chikungunya virus diseases		x			x			
Chemical	Treatment of Bardet Biedl syndrome			x			x	x	
Chemical	Treatment of NSCLC	x						x	
Chemical	Treatment of lung diseases	x						x	
Biological	Treatment of type-1 diabetes	x					x	x	
Chemical	Treatment of schistosomiasis		x					x	
Biological	Treatment of protein C deficiency	x						x	
Biological	Treatment of glioblastoma			x				x	x
Chemical	Treatment of Huntington's disease	x					x	x	
Advanced Therapy	Treatment of mucopolysaccharidosis type I			x		x	x	x	x
Chemical	Treatment of chronic kidney disease	x					x	x	
Biological	Treatment of NSCLC	x						x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 65 Scientific Advice letters - 39 Initial Scientific Advice, 12 Follow-up Scientific Advice, 8 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 17-20 May 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 76 new Requests for which the procedure started at the SAWP meeting held on 03-06 May 2021. The new requests are divided as follows: 39 Initial Scientific Advice, 16 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.